

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

<b>NEW LIFE HOMECARE, INC;</b>	<b>:</b>	<b>No. 3:08cv1438</b>
<b>J.R., a minor, by and through his</b>	<b>:</b>	
<b>natural parent and guardian, Dawn</b>	<b>:</b>	<b>(Judge Munley)</b>
<b>E. Litchey;</b>	<b>:</b>	
<b>A.R., a minor, by and through his</b>	<b>:</b>	
<b>natural parent Dawn E. Litchey, and</b>	<b>:</b>	
<b>Dawn E. Litchey, individually,</b>	<b>:</b>	
<b>v.</b>	<b>:</b>	
<b>BLUE CROSS BLUE SHIELD OF</b>	<b>:</b>	
<b>MICHIGAN, and</b>	<b>:</b>	
<b>BLUE CARE NETWORK OF</b>	<b>:</b>	
<b>MICHIGAN,</b>	<b>:</b>	
<b>Defendants</b>	<b>:</b>	

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**MEMORANDUM**

Before the court is plaintiffs' motion for a temporary restraining order (TRO) and preliminary injunction (PI) (Doc. 13). The parties have briefed the issues and the court has entertained testimony. The matter is thus ripe for disposition.

**Background<sup>1</sup>**

The case grows out of the refusal of the defendants, Blue Cross Blue Shield of Michigan ("Blue Cross"), to purchase medications to treat Minor Plaintiffs A.R. and J.R. ("minor plaintiffs") for hemophilia from Plaintiff New Life Homecare. Blue Cross administers the minor plaintiffs' insurance policy, which is provided for them through

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<sup>1</sup>The court here provides only a brief recitation of the facts and procedural history of the case. Additional facts will be added as appropriate in the discussion portion of this opinion.

their fathers' employment with General Dynamics Corporation. Plaintiffs seek a injunction from the court compelling the defendants to continue purchasing this medication and other medication-related services from New Life.

A.R. and J.R., the minor plaintiffs in this case, suffer from hemophilia, a genetic disorder marked by a deficiency in essential blood-clotting proteins in a patient's body.<sup>2</sup> Patients treat their condition by using a number of injectable medications which aid in the blood-clotting process. These medications, which come in a variety of formulations, are generally referred to as "factor."<sup>3</sup> J.R., who is A.R.'s older brother, suffers from a more severe form of the disease. He has developed an "inhibitor" to factor that often prevents the medication from working. His disease is more debilitating as a result, and he requires different, more extensive and more often emergency treatment than his brother. Since August 1, 2008, they

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<sup>2</sup>"Hemophilia is a rare, inherited bleeding disorder in which your blood doesn't clot normally. If you have hemophilia, you may bleed for a longer time than others after an injury. You may also bleed internally, especially in your knees, ankles, and elbows. This bleeding can damage your organs or tissues and, sometimes, be fatal. People born with hemophilia have little to none of a protein needed for normal blood clotting. The protein is called a clotting factor. There are several types of clotting factors, and they work together with platelets to help the blood clot. Platelets are small pieces of blood cells that are formed in the bone marrow. They play a major role in blood clotting." U.S. Department of Health and Human Services, National Heart Lung and Blood Institute, Diseases and Conditions Index, HEMOPHILIA: WHAT IS HEMOPHILIA?, available at [http://www.nhlbi.nih.gov/health/dci/Diseases/hemophilia/hemophilia\\_what.html](http://www.nhlbi.nih.gov/health/dci/Diseases/hemophilia/hemophilia_what.html).

<sup>3</sup>"The main treatment for hemophilia is called replacement therapy—giving or replacing the clotting factor that's too low or missing. Concentrates of clotting factor VIII (for hemophilia A) or clotting factor IX (for hemophilia B) are slowly dripped in or injected into a vein." Id., How is HEMOPHILIA TREATED?, available at [http://www.nhlbi.nih.gov/health/dci/Diseases/hemophilia/hemophilia\\_treatments.html](http://www.nhlbi.nih.gov/health/dci/Diseases/hemophilia/hemophilia_treatments.html).

have received these medications through a home-delivery pharmacy, Accredo (also known as Hemophilia Health Services), which provides them their medications at home on both a regular and emergency basis. Formerly, the minor plaintiffs received their home-care medications through Plaintiff New Life, another licensed pharmacy that specializes in care for those with hemophilia and other blood-related diseases. In their complaint, plaintiffs allege that defendants engaged in unfair practices in order to sever their relationship with New Life and replace it with Accredo. They also contend that the services provided by Accredo are inferior and fail to provide them with necessary ancillary services, such as counseling, pastoral support, and medical devices. Combined with a longer delivery time for emergency medications, plaintiff alleges, Accredo's service is substandard and endangers their health.

Plaintiffs filed a complaint in this court on July 31, 2008. (Doc. 1). Count I raises a breach of fiduciary duty claim pursuant to the Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1109 and 1132(A)(2). Count II is a claim pursuant to 29 U.S.C. § 1133(2) for breach of duties owed to Plaintiff New Life. New Life alleges that defendants have not provided payment for valid claims submitted pursuant to the minor plaintiffs' policy. Count III is a state law conversion action, contending that Defendant Blue Cross Blue Shield has refused to reimburse New Life for valid claims. This count seeks nearly \$4 million in damages. Count IV, brought pursuant to the Hobbs Act, 18 U.S.C. § 1951, alleges that defendants

engaged in a scheme to obstruct, delay and affect commerce and the movement of specialty drugs from wholesalers to New Life and from New Life to the Minor Plaintiffs. Count V alleges discrimination based on health status in violation of 26 U.S.C. § 9802(a)(1) and 29 U.S.C. § 1182(a)(1), contending that the defendants discriminated against the plaintiffs on the basis of their medical condition by refusing to provide them with services from New Life. Plaintiff New Life seeks nearly \$4 million it claims Blue Cross has unlawfully withheld on valid claims. The minor plaintiffs also seek monetary damages as compensation for the discrimination they allegedly faced from defendants' conduct.

Plaintiffs filed a motion for a TRO and PI on July 31, 2008. (Doc. 2). The court set a date for a hearing on the TRO (Doc. 4), but the parties informed the court that they had entered into a partial settlement agreement and no hearing on the application was necessary. (Doc. 10). On September 30, 2008, defendants filed a motion to dismiss the complaint and for summary judgment. (Doc. 11).

On October 3, 2008, the plaintiffs renewed their motion for a TRO and PI. (Doc. 13). The plaintiffs represent to the court that the defendants have allowed plaintiffs to resubmit the claims already filed for processing. The payments allegedly due from defendants to Plaintiff New Life, therefore, are not the subject of the instant application. Instead, plaintiffs contend that the court's failure to grant injunctive relief will prevent the minor plaintiffs from obtaining life-saving medical treatment. They seek an order from the court restraining and enjoining defendants from adjusting,

altering, modifying, withholding or retaining any portion of any future remittances for prescription medications, products and services provided by New Life and an order restraining and enjoining the defendants from discriminating against Scranton-area employees and dependents who are hemophiliacs by preventing their access to products and services supplied by New Life.

The court held a hearing on this motion on October 8, 2008. At the close of the hearing, the court ordered the parties to file briefs on their positions. The court also ordered the parties to depose one of the minor plaintiffs' treating physicians and to file supplemental briefs that addressed that testimony. They did so, bringing the case to its present posture.

### **Jurisdiction**

Because this case is brought pursuant to ERISA, 29 U.S.C. § 1132(e)(1), et seq., the court has jurisdiction pursuant to 28 U.S.C. § 1331 ("The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."). The court has jurisdiction over plaintiffs' state law claims pursuant to 28 U.S.C. § 1337(a) ("In any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.").

### **Legal Standard**

The Third Circuit Court of Appeals has outlined four factors that a court ruling on a motion for a preliminary injunction must consider: (1) whether the movant has shown a reasonable probability of success on the merits; (2) whether the movant will be irreparably injured by denial of the relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether granting the preliminary relief will be in the public interest. Crissman v. Dover Downs Entertainment Inc., 239 F.3d 357, 364 (3d Cir.2001). These same factors are used to determine a motion for a temporary restraining order. Bieros v. Nicola, 857 F. Supp. 445, 446 (E.D.Pa.1994).

The above factors merely “structure the inquiry” and no one element will necessarily determine the outcome. The court must engage in a delicate balancing of all the elements, and attempt to minimize the probable harm to legally protected interests between the time of the preliminary injunction to the final hearing on the merits. Constructors Association of Western Pa. v. Kreps, 573 F.2d 811, 815 (3d Cir.1978). The movant bears the burden of establishing these elements. Adams v. Freedom Forge Corp., 204 F.3d 475, 486 (3d Cir.2000). We will address each injunction factor separately.

## **Discussion**

The court will address each of the four TRO-related factors in turn.

### **i. Reasonable Probability of Success on the Merits**

First, the parties dispute whether plaintiffs could prevail in their underlying

claims against the defendants. The claim in question here is plaintiffs' allegation that defendants' decision to use Accredo instead of New Life to supply medications violates ERISA by discriminating against hemophiliacs in the Scranton area. The parties disagree over whether the provisions of ERISA, 29 U.S.C. §§ 1182(a)(1), and the Health Insurance Portability and Accountability Act ("HIPAA"), 26 U.S.C. § 9802(a)(1), cited by the plaintiffs apply to this situation.

The provisions that plaintiff cites use identical language to prohibit health care plans from discriminating against potential enrollees because of their health care status or history. The statutes establish that "a group health plan may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based" the health status of "the individual or a dependent of the individual." 26 U.S.C. § 9802(a)(1)(A); 29 U.S.C. § 1182(a)(1)(A) (adding to section (1) to apply as well to "a health insurance issuer offering group health insurance coverage in connection with a group health plan."). In addition, the statutes provide that "paragraph (1) shall not be construed—(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or (B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage." 29 U.S.C. § 1182(a)(2)(A-B). This section of the law does not apply to this case. The evidence at the hearing indicates that the minor plaintiffs are

enrolled in the plan and have not been denied services provided by the plan. Their eligibility to enroll in the plan, therefore, was not affected by their health status.

Plaintiffs could not prevail on a claim under this provision.

Accordingly, this factor weighs heavily against the minor plaintiffs. Their situation—a disagreement about which provider should provide the services for which the plan makes them eligible—is not covered by the ERISA and HIPAA provisions they cite. The court lacks authority to order the defendants to use a particular provider for services, which is the only remedy that would satisfy the minor plaintiffs' demands. See, e.g., Bellas v. CBS, Inc., 221 F.3d 517, 522 (3d Cir. 2000) (finding that “ERISA neither mandates the creation of pension plans nor in general dictates the benefits a plan must afford once created . . . Only the plan itself can create an entitlement to benefits.”). For the particular plaintiffs seeking the injunction, then, the court finds that they do not have a reasonable likelihood of prevailing on the merits of their claim.<sup>4</sup>

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<sup>4</sup>The parties also disagree over whether defendants have authority to make changes to benefits under the plan. Defendants contend that only General Dynamics has authority to make changes in the plan, and that Blue Cross Blue Shield serves only as a claims administrator for that plan. As such, any claims that plaintiffs have about the decision to use Accredo and not New Life must be addressed to General Dynamics, the party that made the decision in the case. Plaintiffs insist that Blue Cross Blue Shield made the decision to stop using New Life, and that Blue Cross can therefore be liable for any discrimination that the minor plaintiffs faced as a result. The court finds that whether the defendants made the ultimate decision to terminate New Life as a provider under the plan is immaterial to the question of whether minor plaintiffs can sue anyone for discrimination under either HIPAA or ERISA. Since the plaintiffs cannot bring an action under the acts regardless of who made the decision to use New Life, the court will not address the likelihood of proving that plaintiffs could prevail against any particular party.

Though this factor tilts the balance almost irretrievably towards the defendants, the court will examine the other factors in order to engage in the balancing required by the case law. See Kreps, 573 F.2d at 815 (finding that “these factors structure the inquiry, however, no one aspect will necessarily determine its outcome. Rather, proper judgment entails a ‘delicate balancing’ of all elements.”).

#### **ii. Irreparable Harm to Plaintiff from Delay**

The plaintiffs contend that they will suffer irreparable harm if the court does not order that they continue to receive factor from New Life.<sup>5</sup> Plaintiffs argue that Accredo cannot deliver those drugs quickly enough to prevent the life-threatening complications that can arise from a severe bleeding episode, and that they fail to provide the ancillary services necessary to provide them with adequate care.

Plaintiff Dawn Litchey, mother of the minor plaintiffs A.R. and J.R., testified about her children’s condition. Her older son, J.R., has developed a “severe inhibitor” which prevents Factor VIII, a frequently prescribed hemophilia medication, from working to stop him from bleeding. (Transcript of hearing held October 8, 2008, Exh. 8 to Defendants’ Brief in Opposition to Plaintiffs’ motion for a TRO and PI

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<sup>5</sup>The plaintiffs do not argue that Plaintiff New Life will suffer any particular harm from the delay of a decision on the case. As such, the court will concentrate only on the arguments made on behalf of injury to the minor plaintiffs. In any case, the plaintiffs have not presented any evidence to indicate that New Life would be forced out of business as a result of the failure of the defendants to purchase factor from the company. Without such evidence, the court will not find an injunction in a contract action like the instant one appropriate. New Life should proceed with their contract to recover for their alleged damages.

(Docs. 27-2-4) (hereinafter "T") at 16). J.R. "has to use bypass factor IX and factor VII products." (Id.). J.R. has suffered episodes of "continuous bleeding in his joints" that led him to lose the cartilage in his knees and elbows, limited his range of motion to the point where he could barely walk, and caused arthritis in his hips, knees and elbows." (Id. at 17). While Ms. Litchey gives J.R.'s brother A.R. his medication every other day through an IV, J.R. receives factor VIII daily and travels to a Philadelphia hospital weekly for other therapy. (Id. at 18). When J.R. sufferd acute bleeding, his mother must administer him two drugs immediately. (Id.). She delivers one drug every two hours, and the other every eight-to-twelve hours. (Id.). She may follow this protocol for days, depending on the nature of the bleed. (Id.). Dawn Litchey cannot predict when or how much of these drugs she will need, because they apply to emergency situations. (Id. at 19). Accredo would not be able, she contends, to provide her children with the needed drugs "in a timely manner" if an emergency were to arise, because they need the drugs "immediately" and Accredo shipments sometimes take four hours to arrive. (Id. at 30). New Life, by contrast, can supply the necessary medication within twenty minutes. (Id.). Taking her children to a local hospital in such a situation is not always an option; sometimes the hospitals lacked the proper drugs, and sometimes they found the children's situation too complicated and sent them to larger hospitals. (Id. at 31).

Ms. Litchey described one situation where she claimed the inability of Accredo to deliver factor when she requested it had endangered her son's health. Her

younger son, A.R., had suffered a knee bleed. (Id. at 20). A.R., “who is not nearly as fragile as [J.R.]” needed factor in the morning. (Id.). She had the drugs on hand. (Id.). Later in the day, however, she needed more factor. (Id.). Ms. Litchey called Accredo, which promised to deliver the drugs by 8 p.m. (Id.). The factor failed to arrive by 9 p.m., though she eventually obtained the necessary medication, (Id.).

Ms. Litchey testified that A.R. would suffer long-term damage from this delay in receiving medications, but offered no medical evidence for that conclusion. (Id. at 38-39). She had not “asked [her] doctor” for an opinion because twenty-six years of experience with hemophilia had taught her the consequences of a bleed. (Id. at 39). On cross-examination, however, Ms. Litchey admitted that though she was aware of the bleed in the morning, she did not order the factor until the afternoon. (Id. at 44). A.R., she testified, “usually responds” to the first dose he receives. (Id.). Thus, she did not consider his situation an “emergency” one, and waited to see if he would respond before calling Accredo. (Id. at 45). Only when A.R. was still bleeding in the afternoon did Ms. Litchey seek additional medication, because the situation “became a little critical when [she] realized that [A.R.] didn’t respond to his factor like he normally does.” (Id.).<sup>6</sup>

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<sup>6</sup>Maureen McCollough, Accredo’s Clinical Director, testified that the company attempts to avoid situations like the one that A.R. faced by having patients “keep four doses in the home, and when they get to four doses, to give us a call. That will give us enough time to get factor out to them without any type of emergency rush on it.” (Deposition of Maureen McCollough, Exh. G. to Plaintiff’s Brief in Support of Motion for TRO and PI (Doc. 29-7)(hereinafter “McCollough Dep.”) at 14). In the case of J.R., McCollough conceded that four doses of factor on hand was insufficient. (Id. at 32). She argued, however, that the branch office in New Jersey kept “inventory product in the

Other evidence indicates that the provisions for delivery of medicines that Accredo offers protects the health of the minor plaintiffs. One of A.R. and J.R.'s treating physicians, Dr. Leslie Raffini, testified in a supplemental deposition that the boys both suffer from "severe hemophilia." (Deposition Transcript of Dr. Leslie Raffini, Attached as Exh. 13 to Defendants' Supplemental Brief in Opposition to Plaintiffs' Motion for a TRO and PI (Doc. 33) (hereinafter "Raffini Dep.") at 7). Dr. Raffini reported that A.R., the younger of the brothers, "is treated with infusions of recombinant factor every other day to prevent bleeding episodes." (Id.). With this treatment, A.R. is "actually able to lead a relatively healthy, regular lifestyle." (Id.). He could go to school and participate in some sports and activities. (Id.). J.R., A.R.'s sixteen-year-old brother, suffers from a more severe form of the disease. (Id.). He has developed an "inhibitor, . . . an antibody that prevents him from responding to recombinant factor VIII infusions." (Id.). This "complication," means that J.R. cannot be treated with "regular infusions of factor VII to prevent bleeding." (Id. at 7-8). Instead, J.R. receives both factor and "alternative products in response to bleeding episodes." (Id. at 8). The fragility of J.R.'s condition has caused him to "[develop] significant hemophiliac arthropathy in many of his joints and [he] has frequent bleeding episodes which are difficult to manage." (Id. at 8). Bleeding in J.R.'s joints often lasts for weeks, does not respond to treatment, and requires

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branch itself for [J.R.] so we can get it right out to him and we can make it to his home in an hour and 45 mintues." (Id.).

changes to his treatment “on a daily basis.” (Id.).

Dr. Raffini explained the treatment J.R. receives during one of these bleeding episodes. He treats a bleeding episode by using two products, “recombinant factor VIIa” (“factor VIIa”) and “Factor Eight Inhibitor Bypassing Activity” (“FEIBA”). (Id. at 9). According to Dr. Raffini, J.R. often makes the initial decision on how to use these two products, which “can be dosed differently at different time frequencies.” (Id.). J.R. “may treat himself with three doses of factor VIIa every two hours and see what the response is like,” or he might “start with FEIBA and treat himself every eight hours.” (Id.). If those drugs fail, he can turn to others, or other combinations of drugs. (Id.). J.R. frequently seeks “advice” from doctors “in the midst of treating a complicated joint bleed,” and his doctors “work with [the patient] to try to come up with some sort of balance of those two drugs that seems to stop the bleeding.” (Id. at 9-10).

Dr. Raffini also reported she could not specify a precise amount of factor necessary for J.R. to have on hand to treat severe bleeds. (Id. at 10). Instead, doctors would “look at his most recent bleeding episodes and make sure that he has a sufficient amount for a period of a couple of weeks.” (Id.). J.R.’s situation was different from his brother’s, “who usually gets a one-month supply of prophylaxis with a couple of extra episodes for bleeding.” (Id.). J.R.’s medication requirement “changes on a frequent basis.” (Id.). At times, as well, J.R. found that neither product worked for a specific bleeding incident, and he would be required to travel to

the Children's Hospital of Philadelphia ("CHOP") for treatment.<sup>7</sup> (Id. at 11). Dr. Raffini also testified that a doctor could "predict" how much product J.R. would need "for the next week—or at least a maximum." (Id. at 12). The products cannot be taken "continuously," and "the maximum amount of FEIBA he could receive on a day would be three doses." (Id.). A patient receiving that much FEIBA could not receive more than three doses of factor VIIa on the same day; "[s]o, there are maximums," and "assuming the worst-case scenario that he's having continual bleeding, you could predict what his requirement would be." (Id.). Thus, "the family can look and see what they have in stock and should be able to predict what their need is within at least two to three days," even in the case where a patient suffers from a severe bleed. (Id. at 12-13). In addition, Dr. Raffini found it fair to say that "neither the health of [J.R.] or [A.R.] would be adversely affected if factor can be ordered and delivered to their home within five hours." (Id. at 20).

The testimony also revealed that services beyond the provision of drugs are also important for hemophilia patients. Ms. Litchey testified that she had "been a hemophilia mom for over 26 years," and had used various companies to obtain medicine. (T. at 21). New Life, she found, offered "services . . . tailored" to hemophiliacs like her sons. (Id.). New Life's pharmacy was nearby, and she could

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<sup>7</sup>Dr. Raffini reported that "the fact that some of these bleeds seem to last for days to weeks suggests that the products aren't working very well. Fortunately, bleeding into a joint is a confined space, so he couldn't bleed to death from a joint bleed, but if he were having internal bleeding we would have him at CHOP and we would consider different combinations of those two drugs." (Raffini Dep. at 11).

get factor for her sons in twenty minutes. (Id.). She need not worry about waiting hours to receive it. (Id.). The company also proved more responsive to her specific concerns and requests than other suppliers. (Id. at 22-23). New Life provides a number of “ancillary” services Ms. Litchey considers vital to her sons’ care, such as “Ace bandages, wheelchairs, [and] nursing services.” (Id. at 24). During an incident the previous summer when her son had to be flown by helicopter to a hospital in Philadelphia, the company vice-president, chief executive officer and a nurse all arrived at the scene to assist Ms. Litchey; they even arranged for transportation to the hospital for her.<sup>8</sup> (Id. at 24).

Ms. Litchey testified that Accredo provides none of these sorts of ancillary services. (Id. at 24). During a previous period when her children received coverage from Accredo, Ms. Litchey turned to the company for support services. The social worker she sought help from covered a large territory, and never bothered to call her back. (Id. at 25). The company also made errors in delivery. (Id.) Ms. Litchey found that “I didn’t get anything from Accredo, but the actual factor.” (Id.). New Life, by contrast, “understands the complexity with living with a chronic condition” and their services are “all about the client; counseling, support, adjustment to disability, illness or loss, information, guidance, family relationship issues, depression. See, they actually get it.” (Id. at 27).

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<sup>8</sup>Dawn Litchey works in marketing for New Life and with clients who suffer from hemophilia. (T. at 37). Her compensation does not depend on whether her children use the company’s services. (Id.).

Dr. Raffini also testified about the differences between the services provided by Accredo and New Life. Dr. Raffini had “no opinion” as to whether there was any “medical necessity” in having J.R.’s medical supplier within twenty minutes of his home, as New Life is, or more than two-and-one-half hours away, as with Accredo.<sup>9</sup> (Raffini Dep. at 16). At the same time, Dr. Raffini argued that “in hemophilia . . . we try to support our families in something we call ‘patient choice.’” (Id. at 17). Though she recognized “that insurance companies may regulate home care choice . . . we do support our families’ choice, right to choice.” (Id.). Shown a list of the services

<sup>9</sup>Indeed, the dispute here is really about what company should supply the factor that minor plaintiffs keep at home, not about whether plaintiffs will be able to receive factor. The court finds that both New Life and Accredo have developed an adequate system for providing home delivery of factor. Michelle Fullerton, director of care management services for Blue Cross Blue Shield of Michigan, described the purpose of home treatment as supplied by companies like Accredo and New Life: “The goal is to have enough factor in the house, and that’s why it is called home infusion factor; to avoid having to bring the patient to the emergency room or to the hospital. This whole business was created to allow self-infusion to have emergency treatment at the time of the bleed . . . you can have extra factor stored in the fridge in your house for up to two years, and that factor can be there for a bleed. So, when the bleed begins, and this is an emergency bleed, not your standard infusion, there should be some in your fridge.” (Deposition of Michelle Fullerton, Exh. 11 to Defendants’ Brief in Opposition to Plaintiffs’ Motion (Doc. 27-8) (hereinafter “Fullerton Dep.”) at 12-13). Once a dose is used the patient is required to contact the pharmacy immediately to replenish the backup supply. In that way, the patient is never to encounter a situation where a bleed occurs and no factor is available at home. Blue Cross thus works with patients to insure that they have factor on hand for emergencies and “to accommodate that time period of delivery of further factor.” (Id. at 13). If, however, a family for some reason lacked a proper dose of factor at home, they would be forced to go to a hospital. (Id.). In that situation, a hospital may not have the proper drug on hand. (Id.). Hospitals negotiate with various companies to provide the factor: “it could be New Life; it could be Accredo; it could be Corum. It could be hundreds of other specialty pharmacies that are in this business. They negotiate their own rates to deliver that factor to the hospital.” (Id. at 13-14). No matter which company supplied the factor to the plaintiff in that situation, Fullerton testified, the hospital would be paid under the terms of the General Dynamics plan. (Id. at 14).

provided by New Life which are unavailable through Accredo, such as “vocational assessments, transportation to hospital, support groups, domestic violence support or counseling, depression counseling, substance abuse counseling, chemical dependency counseling, family relationship counseling, and crisis intervention counseling,” Dr. Raffini was unable to render an opinion as to whether failing to receive those services would jeopardize A.R. and J.R.’s health. (Id. at 22-24). Raffini was not “aware that a home company is responsible for providing all of these services,” but found them to be “good services and there would be an advantage to having a home care company that provided those services as part of their care.” (Id. at 26-27).

The court is sympathetic to plaintiffs’ desire to use New Life as their provider, since the company is reliable, sympathetic and nearby. The court finds, however, that the minor plaintiffs have not established that they will be irreparably harmed by the requirement that they use Accredo. The evidence indicates that Accredo supplies the necessary medications in a timely fashion; plaintiffs’ own doctor testified that plaintiffs will not be deprived of the medications they need because of their insurer’s requirement that they obtain them from Accredo.<sup>10</sup> Dr. Raffini had no

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<sup>10</sup>Dr. Raffini testified that the way that hemophilia treatment works limits the amount of factor that can be provided on any given day and makes its use fairly predictable over short periods of time. (See Raffini Dep. at 11-12) (finding that “there are maximums. You can—sort of assuming the worst-case scenario that [J.R.]’s having continual bleeding, you could predict what his requirement would be . . . I think we should be able to look—the family can look and see what they have in stock and should be able to predict what their need is within at least two to three days.”). Accordingly, proper use of the home-care system should ensure that a patient always have an adequate supply of medication on

opinion about whether the minor plaintiffs would receive any benefit from being much closer to New Life than Accredo. The purpose of the services provided by both Accredo and New Life, as explained in note 9, *supra*, is to supply medication for use in the home so patients can avoid unnecessary hospital trips. Under the system used by both New Life and Accredo, patients keep several doses of medication on hand to cover a bleed. They order new medication when a bleed starts, and the company supplies the needed medication and replaces the reserve supply.

Following this system, a patient can avoid any shortage. Though plaintiffs complain of an incident where A.R. did not have factor available to him when he needed it, the evidence indicates that his mother did not consider the situation an emergency and did not place an order for the medication until long after she realized that she might need it. Moreover, if faced with an emergency where factor is unavailable, plaintiffs can go to the hospital. Hospitals can obtain medication from the fastest available source, and the medications are covered by plaintiffs' insurance plan, no matter which company (including New Life) supplies it.

The court is likewise sympathetic to plaintiffs' desire to make use of the extensive ancillary services New Life offers.<sup>11</sup> The court emphasizes that the issue

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hand for emergency situations.

<sup>11</sup>Testimony indicates that Accredo is not as devoid of such services as plaintiffs claim, though the court is not prepared to judge whether the quality of such services is comparable. Maureen McCollough testified that Accredo provides patients with "Cryo Cuffs and ace bandages, cold packs, if they need 'em, helmets, knee pads, elbow pads, all the infusion supplies that the client will need." (McCollough Dep. at 9). The company also provides "community advocates" who offer "health and life insurance counseling . . . school

here, however, is not which provider offers the best services, but whether the services provided by Accredo are so inadequate that the plaintiffs would suffer irreparable harm from being forced to use them. Despite the sympathy that the court feels for the enormous challenges faced by the minor plaintiffs and their caregivers, plaintiffs have not put forth evidence to establish such potential harm, and the court finds that this factor weighs against them.

### **iii. Harm to the Nonmoving Party**

The court must next consider the harm to the non-moving party. Defendants argue that they will be harmed because they do not have the authority to change the plan they administer for General Dynamics, and they would violate ERISA if they did so. Defendants also argue that the court should not grant the requested relief because the harm from the injunction will fall not on the defendants, but on General Dynamics, a non-party to the case. Moreover, the costs to General Dynamics for using New Life's services is far greater than the cost of using Accredo, and that cost will again fall on General Dynamics. Plaintiffs contend that New Life is willing to accept the industry's standard price for its service, and defendants therefore will

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and employment advocacy." (*Id.* at 27). Patients receive, free of cost, "help with transportation, wheelchairs, crutches, things like that." (*Id.* at 28). The company does not provide, however, the sort of depression, substance abuse, chemical dependency, family relationship, or crisis intervention counseling that New Life does. (*Id.* at 29). While New Life's service may very well be superior, the court is aware that the inquiry here is not which company's services are better, but whether the minor plaintiffs will suffer irreparable harm from using Accredo. Because the evidence indicates that Accredo provides factor in a timely fashion and that the plaintiffs have a means for insuring that they have or can obtain the necessary medication without undue delay, the court is forced to conclude that no irreparable harm exists.

incur no costs greater than if they obtained the medicines from Accredo.

The parties disagree about the potential cost of having plaintiffs' drugs supplied through New Life. Plaintiffs point to testimony from Linda Abner, accounts manager and corporate treasurer for New Life. (T. at 57). Abner testified that New Life would accept the Average Wholesale Price (AWP) minus fifteen percent as payment for the drugs they supplied to the minor plaintiffs. (Id. at 71). Abner contended that this price was "the industry standard," and asserted that she knew this to be the price because of her experience with New Life's "contracted pricing with other insurance companies." (Id.). On cross examination, however, Abner admitted that around fifty drugs had "been singled out and labeled as injectable drugs and targeted for lower reimbursements" in agreements between insurers and the pharmacy. (Id. at 72). The drugs used by the minor plaintiffs were some of the drugs reimbursed at less than AWP minus fifteen percent. (Id.). Abner's knowledge of pricing, moreover, was limited to her experience with New Life; she had no knowledge of how other providers priced their medications. (Id. at 74). She did not know the amount Accredo charged for factor. (Id. at 75).

Lawerence Kisch, director of benefits, human resources information systems and administration for General Dynamics, also testified at the hearing. Kisch related that General Dynamics "own[ed]" and "designed" the health-care plan that covered the minor plaintiffs. (Id. at 78). General Dynamics, not Blue Cross Blue Shield of Michigan, paid any claims that arose under the policy. (Id. at 79). Only General

Dynamics has authority to change the terms of the plan, and the plan agreement gives the company the right to amend the plan at any time. (Id. at 79, 82). The company had paid more than \$6 million to provide services to the minor plaintiffs during the period they were covered by the plan. (Id. at 82-83). Under the plan's terms, General Dynamics could have put a ceiling on total coverage and avoided incurring future liability for covering those plaintiffs. (Id. at 83). Though company officials "had long discussions" about whether to cap the plaintiffs' coverage, they decided instead to "[look] at every other avenue" for cutting costs. (Id. at 84). After examining different measures, officials determined that using Accredo instead of New Life would save the company \$700,000 over six months. (Id.). The company adopted that measure. (Id.). Kisch also testified that the company had amended the plan to make Accredo the sole provider of factor and other hemophilia drugs under the plan. (Id. at 98). Blue Cross Blue Shield could only use General Dynamics' money to pay a provider authorized under the plan; if Blue Cross attempted to pay an unauthorized provider, Kisch predicted that "[w]e would probably attempt to have that come out of their pocket." (Id. at 98-99).

The court finds that the harm to the non-moving party would be significant. The testimony indicates that New Life's pricing is significantly higher than Accredo's. Though Abner claimed that the company would not charge more than the "industry standard" price for any products delivered, she based her description of the "industry standard" on her experience with the prices that New Life charges various insurance

plans for their products. Abner admitted she had no basis for comparison to Accredo's prices, and plaintiffs have provided no other evidence by which the court could compare New Life's prices to Accredo's. Instead, the plaintiffs' position appears to be that the court should accept New Life's representations that it charges the "industry standard" price, even though the testimony indicates that the basis for General Dynamics' decision to switch to a different provider was the significantly higher prices New Life charges. Still, the testimony indicates that using New Life would cost General Dynamics hundreds of thousands of dollars more over a matter of months than using Accredo. Such increased costs are a significant burden on General Dynamics as the party that funds the policy. Moreover, General Dynamics is not a party to this action. Forcing Blue Cross Blue Shield to pay claims to New Life, despite the terms of a policy that Blue Cross cannot amend, may expose the defendants to a liability they would normally not have to pay. The court therefore finds that the harm to the defendants from granting the injunction outweighs the damage to the minor plaintiffs from failing to grant that injunction.

#### **iv. Public Interest**

Plaintiffs did not address the public interest in an injunction in this case during their opening brief, but did so in a supplemental brief meant to address the additional testimony from Dr. Raffini. They argue that a public interest exists in protecting the health of the minor plaintiffs, as well as in giving the public a choice about which medical providers they use to treat debilitating conditions. Defendants argue that

there is no public interest in requiring a health care plan to expand its benefits to additional providers or to require a plan to reimburse providers for medications at higher rates than the plan has negotiated with an exclusive provider.

The court agrees that the public interest would not be served by an injunction in this case. The court has already addressed plaintiffs' argument that their health depends on the use of New Life. The court is sympathetic to the plaintiffs' argument that they should have more say in choosing the parties that provide them with medical services. The Congress, however, has determined that the public interest is met by mandating access to health care regardless of health condition, not by mandating access to a particular provider. The provisions of the federal statute that gives the court reason to hear this case focus not on patients' right to choose their providers, but on the right of patients to have access to health care, regardless of their medical condition. Congress has also provided patients with a right to fair administration of their claims. See, e.g., Nazay v. Miller, 949 F.2d 1323, 1329 (3d Cir. 1991) (finding that "ERISA's concern is with the *administration* of benefit plans and not with the precise design of the plan."); Goldstein v. Johnson & Johnson, 251 F.3d 433, 441 (3d Cir. 2001) (finding that "ERISA was enacted to ensure that employer-provided benefit plans are safeguarded and maintained so as to be available to employees when they are due. The Act does not mandate that an employer provide benefits, and has nothing to say about how these plans are to be designed."). The minor plaintiffs here do not lack access to health care, and have

presented no evidence that they have been refused the benefits their plan provides. As such, the public interest as expressed by ERISA has been met, and the court finds that this factor also weighs against granting an injunction.

### **Conclusion**

Because all of the factors in question weigh against granting injunctive relief in this matter, the court will deny plaintiffs' motion for a TRO and PI. An appropriate order follows.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

<b>NEW LIFE HOMECARE, INC,</b>	:	<b>No. 3:08cv1438</b>
<b>J.R., a minor, by and through his</b>	:	
<b>natural parent and guardian, Dawn</b>	:	<b>(Judge Munley)</b>
<b>E. Litchey,</b>	:	
<b>A.R., a minor, by and through his</b>	:	
<b>natural parent Dawn E. Litchey; and</b>	:	
<b>Dawn E. Litchey, individually,</b>	:	
:		
<b>v.</b>	:	
:		
<b>BLUE CROSS BLUE SHIELD OF</b>	:	
<b>MICHIGAN, and</b>	:	
<b>BLUE CARE NETWORK OF</b>	:	
<b>MICHIGAN,</b>	:	
<b>Defendants</b>	:	

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**ORDER**

**AND NOW**, to wit, this 4th day of November 2008, the plaintiffs' motion for a temporary restraining order and preliminary injunction (Doc. 13) is hereby **DENIED**. The plaintiffs are hereby **ORDERED** to file a brief in opposition to defendants motion to dismiss and for summary judgment (Doc. 11) within fifteen (15) days of the date of this order. Failure to file the required brief will result in the defendants' motion being granted.

**BY THE COURT:**

s/ James M. Munley  
**JUDGE JAMES M. MUNLEY**  
**UNITED STATES DISTRICT COURT**